



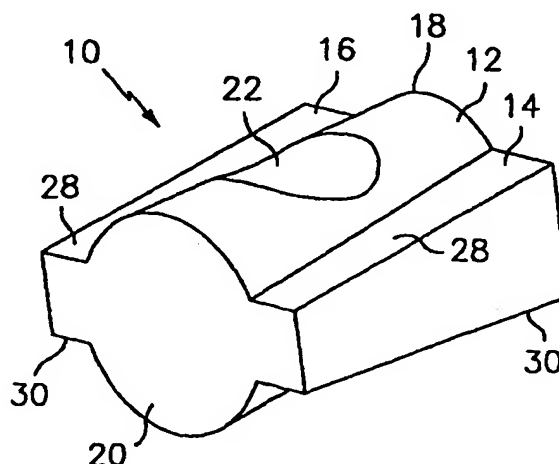
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US00/01766 (22) International Filing Date: 24 January 2000 (24.01.00) (30) Priority Data: 60/116,852           22 January 1999 (22.01.99)   US 09/328,283        8 June 1999 (08.06.99)       US (71) Applicant: OSTEOTECH, INC. [US/US]; 51 James Way, Eatontown, NJ 07724 (US). (72) Inventors: SCARBOROUGH, Nelson, L.; 47 Lambert Johnson Drive, Ocean, NJ 07712 (US). BOYLE, John, W.; 10 Cornell Way, Upper Montclair, NJ 07043 (US). (74) Agents: DILWORTH, Peter, G. et al.; Dilworth & Barrese, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>Without international search report and to be republished          upon receipt of that report.</i>	

(54) Title: INTERVERTEBRAL IMPLANT

## (57) Abstract

An intervertebral implant having a composite wedge/dowel configuration is provided. The intervertebral implant includes a central body portion and a pair of radially extending wings. The radially extending wings can be tapered from a first end of the implant to the second end of the implant along an axis parallel to the longitudinal axis of the central body portion. Alternately, the radially extending wings can be tapered along an axis transverse to the longitudinal axis of the cylindrical body portion or along any other axis between parallel and transverse to the longitudinal axis. A throughbore or plurality of throughbores extend from a top surface of the implant through the implant to a bottom surface of the implant. The implant may be formed from a cortical ring cut from the diaphysis of a long bone by milling the top and bottom surfaces of the cortical ring to form the substantially central body portion and the tapered radially extending wings. The cortical ring is milled such that the intramedullary canal of the cortical ring defines a throughbore in the central body portion of the implant. The sidewalls of the implant may be machined to form a substantially rectangular shape or the implant can be left to have a substantially circular configuration. Alternately, the implant may be formed of any biocompatible material having the requisite strength requirements via any known process, i.e., molding.



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## INTERVERTEBRAL IMPLANT

### BACKGROUND OF THE INVENTION

#### 5 1. Technical Field

The present disclosure relates generally to intervertebral implants and, more particularly, to an intervertebral implant having a composite wedge/dowel configuration suitable for interbody spinal fusion.

#### 2. Background of Related Art

10 Intervertebral implants for fusing together adjacent vertebrae of a spinal column are well known in the surgical arts. Typically, a surgical procedure for implanting an intervertebral implant between adjacent vertebrae is performed to treat back pain in patients with ruptured or degenerated intervertebral discs, spondylolisthesis or other pathologies. A variety of different types of intervertebral  
15 implants have been developed for such a procedure including intervertebral wedge implants, spinal fusion cages and cylindrical threaded bone dowels.

A variety of different types of intervertebral implants have been developed to perform this function including spinal fusion cages, threaded bone dowels and stepped bone dowels. Exemplary implants are disclosed in U.S. Patent  
20 Applications filed on even date herewith, under Certificate of Express Mail Label Nos. EL260888076US and EL071686220US, and entitled "Ramp-Shaped Intervertebral Implant" and "Keyed Intervertebral Dowel", respectively, the entire disclosures of which are incorporated herein by reference.

One fusion cage described in U.S. Patent No. 5,015,247 includes a cylindrical implant constructed from titanium having one closed end, one open end and a series of macro-sized openings formed through a side wall of the implant. The open end of the cylindrical implant is internally threaded and configured to receive a cap. A series of external threads are formed about the circumference of the cylindrical implant. Prior to use, a bone graft of cancellous bone taken from a patient's iliac crest is placed in a press and forced into the hollow body of the cylindrical implant such that cancellous bone extends through the macro-sized openings. The cap is then screwed onto the internally threaded end of the implant. Subsequently, the cylindrical implant is screwed into a previously prepared receiving bed between two adjacent vertebrae.

Because of their simplicity, spinal fusion cages are widely accepted. However, spinal fusion cages suffer from several drawbacks. For example, the cylindrical loading surface area of spinal fusion cages is small, thus two spinal fusion cages are typically required during a surgical procedure. Secondly, spinal fusion cages are made primarily from metal, most notably titanium. This material does not remodel but remains in a patient forever or until it is removed. Since vertebral bodies eventually fuse with the cancellous bone or other bone growth material positioned within the fusion cage, if removal is required, it can be very difficult and dangerous to the patient. Thirdly, spinal fusion cages do not maintain lordosis, thus the natural curvature of the spine is altered. Finally, it is difficult to insert a spinal fusion cage and

achieve equal purchase with the adjacent vertebrae. A spinal fusion cage will often tend to engage one vertebrae more securely than the other.

Wedge implants also suffer from several drawbacks. Although wedge implants have a greater load bearing surface area and are configured to maintain lordosis, wedge implants are more difficult to secure in place since they are not threaded into the vertebrae. Moreover, wedge implants have limited ability to prevent rotational forces between the two vertebrae that are intended to be fused.

Threaded bone dowels also suffer from some of the same drawbacks as spinal fusion cages. Threaded bone dowels have a small loading surface area and they do not maintain lordosis. Furthermore, threaded bone dowels are typically cut from bone with a hollow drill bit and subsequently are threaded. The hollow drill bit is positioned to cut transversely through the bone and the intramedullary canal during the cut. If the distance between the outer surface of the cut dowel and the intramedullary canal does not exceed a predetermined thickness, the dowel must be rejected. Since there is little bone to spare during such a transverse cut, a high percentage of bone dowels cut may be rejected due to anatomical variability between donors.

Accordingly, a need exists for an improved intervertebral implant which maintains simplicity for consistent surgical implantation, creates an improved biomechanical construct when implanted, maintains lordosis, conforms to vertebral endplates, spares the endplates in the load bearing region while perforating them in other areas to gain access to cells in cancellous bone; when produced from bone, can

remodel into bone, can be easily manufactured and addresses other problems associated with current spinal fusion implants.

### SUMMARY

In accordance with the present disclosure, an intervertebral implant  
5 having a composite wedge/dowel configuration is provided. The intervertebral implant includes a central body portion and a pair of radially extending wings. The radially extending wings can be tapered from a first end of the implant to the second end of the implant along an axis parallel to the longitudinal axis of the cylindrical body portion for anterior or posterior insertion. Alternately, the radially extending wings can be tapered  
10 along an axis perpendicular to the longitudinal axis of the cylindrical body portion for lateral insertion or the wings can be tapered along any axis between axis parallel and perpendicular to the longitudinal axis of the implant. A throughbore or a plurality of throughbores extend from a top surface of the implant to a bottom surface of the implant providing a space for boney bridging to occur between the vertebrae which are  
15 intended to be fused. The throughbore(s) is dimensioned to receive growth factors including autograft, allograft, DBM, etc., to stimulate bone healing.

In a preferred embodiment, the implant is formed from a cortical ring allograft cut from the diaphysis or metaphysis of a long bone. The implant can be formed by milling the top and bottom surfaces of the cortical ring to form the central  
20 body portion and the tapered radially extending wings. The implant is milled such that the intramedullary canal of the cortical ring defines a throughbore in the central body

portion of the implant. Thereafter, the sidewalls of the implant may be machined to form a substantially rectangular shape or be maintained in an essentially semi-circular configuration. Alternately, the implant may be formed of any biocompatible material having the requisite strength requirements via any known process, i.e., molding, casting, machining, etc.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Various preferred embodiments are described herein with reference to the drawings wherein:

FIG. 1 is a perspective view of one embodiment of the presently disclosed intervertebral implant;

FIG. 2 is a side view of the intervertebral implant shown in FIG. 1;

FIG. 3 is a top view of the intervertebral implant shown in FIG. 1;

FIG. 4 is a front view of the intervertebral implant shown in FIG. 1;

FIG. 5 is a perspective view of another embodiment of the presently disclosed intervertebral implant;

FIG. 6 is a side view of the intervertebral implant shown in FIG. 5;

FIG. 7 is a top view of the intervertebral implant shown in FIG. 5;

FIG. 8 is a front view of the intervertebral implant shown in FIG. 5;

FIG. 9 is a side view of a long bone;

FIG. 10 is a perspective view of a cortical ring cut from the long bone shown in FIG. 9;

FIG. 11 is a side view of the cortical ring shown in FIG. 10;

FIG. 12 is a perspective view of the cortical ring after the top surface has been milled;

FIG. 13 is a perspective view of the cortical ring after the bottom surface has been milled;

FIG. 14 is a perspective view of the cortical ring after the sidewalls have been machined;

FIG. 15 is a perspective view of the cortical ring after the radially extending wings have been tapered;

FIG. 16 is a perspective view of a third embodiment of the presently disclosed intervertebral implant;

FIG. 17 is a perspective view of a fourth embodiment of the presently disclosed intervertebral implant;

FIG. 18 is a perspective view of a fifth embodiment of the presently disclosed intervertebral implant;

FIG. 18a is a perspective view of a variety of different shaped protrusions;

FIG. 19 is a perspective view of a sixth embodiment of the presently disclosed intervertebral implant;

FIG. 20 is a front view of the intervertebral implant shown in FIG. 19;

FIG. 21 is a top view of the intervertebral implant shown in FIG. 19;



FIG. 22 is a side view of the intervertebral implant shown in FIG. 19;

FIG. 23 is a perspective view of a seventh embodiment of the presently disclosed intervertebral implant;

FIG. 24 is a side view of the intervertebral implant shown in FIG. 23;

5 FIG. 25 is a front view of the intervertebral implant shown in FIG. 23;

FIG. 26 is a top view of the intervertebral implant shown in FIG. 23;

FIG. 27 is a perspective view of an eighth embodiment of the presently disclosed intervertebral implant;

FIG. 28 is a side view of the intervertebral implant shown in FIG. 27;

10 FIG. 29 is a top view of the intervertebral implant shown in FIG. 27;

FIG. 30 is a side view of the intervertebral implant shown in FIG. 27;

FIG. 31 is a top view of a pair of the intervertebral implants shown in FIG. 27 in their implanted positions;

FIG. 32 is a perspective view of another embodiment of the  
15 intervertebral implant;

FIG. 33 is a perspective view of another embodiment of the intervertebral implant;

FIG. 34 is a top view of the intervertebral implant shown in FIG. 33;

FIG. 35 is a front view of the intervertebral implant shown in FIG. 33;

20 FIG. 36 is a side view of the intervertebral implant shown in FIG. 33;

FIG. 37 is a front perspective view of another embodiment of the intervertebral implant; and

FIG. 38 is a side perspective view of the intervertebral implant shown in FIG. 37.

## 5 DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Preferred embodiments of the presently disclosed intervertebral implant will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views.

FIGS. 1-4 illustrate one preferred embodiment of the presently disclosed intervertebral implant shown generally as 10. Briefly, intervertebral implant 10 includes a substantially cylindrical body portion 12 having a pair of radially extending wings 14 and 16. Cylindrical body portion 12 has a first end 18 and a second end 20. Each of radially extending wings 14 and 16 has a trapezoidal shape as viewed from the side of intervertebral implant 10.

15 Cylindrical body portion 10 includes a throughbore 22 which extends from a top surface 24 of body portion 12 to a bottom surface 26 of body portion 12. Throughbore 22 has a central axis which is perpendicular to the longitudinal axis of radially extending wings 14 and 16 and cylindrical body portion 10. Throughbore 22 is dimensioned to receive bone growth material including bone particles and/or a  
20 biocompatible osteoinductive or osteoconductive material. These materials may include cancellous bone, cancellous bone particles, ceramics, polymers, composites, BMP, etc.

Although not shown, additional bores may be formed through wings 14 and 16. These bores may also be packed with bone growth material.

Radially extending wings 14 and 16 each include an upper surface 28 and a lower surface 30. Surfaces 28 and 30 are tapered to converge toward each other from first end 18 of cylindrical body portion 12 to second end 20 of cylindrical body portion 12, i.e., the height of the wings decreases from the first end to the second end of the implant. The wings are shaped in such a fashion as to conform to the vertebral end plates located above and below the implant. Implant 10 is suitable for anterior and posterior insertion. Alternately, surfaces 28 and 30 may be parallel to each other.

Intervertebral implant 10 can be constructed from a broad range of biocompatible materials, such as surgical stainless steel, titanium, ceramic hydroxyapatite, polymers, carbon fiber tantalum, etc., but is preferably constructed from cadaveric human or animal bone or bone composites. Such composites may include those discussed in U.S. Patent No. 5,899,939 to Boyce et al. and in U.S. Patent Application Serial No. 09/256,447 to Boyce et al., the entire disclosures of which are incorporated herein by reference. Intervertebral implant 10 can be used in cervical, thoracic and lumbar spinal fusion procedures. For cervical spinal fusion procedures, in which implants are typically between 8-15 mm in length and 10-14 mm in diameter, bone is preferably obtained from the fibula, radius, ulna or humerus. For thoracic and lumbar spinal fusion procedures in which implants are typically 10-30 mm in diameter and about 14-20 mm in height, bone is preferably obtained from the humerus, femur or

tibia. Alternately, as discussed above, intervertebral implant 10 can be molded or machined from other biocompatible materials including composites made of bone.

Referring to FIGS. 9-15 above, in one preferred embodiment, intervertebral implant 10 is manufactured from a cortical ring C formed by making transverse cuts through a long bone D, along lines A and B as illustrated in FIG. 9. Next, the top 34 of cortical ring C is machined using a milling device (not shown) having a dome or crown configuration to shape one side of cortical ring C to have a semi-cylindrical portion 36 with two radially extending flats 38 (FIG. 12). Cortical ring C is flipped over and the same milling procedure is performed on the bottom surface 40 to form radially extending wings 14 and 16 and cylindrical body portion 12. Next, the front and side surfaces are machined to reconfigure cortical ring C to have a rectangular configuration (FIG. 14). Alternately, this step may be deleted and the implant can retain its original profile which will vary depending on the type of bone being cut. Finally, wings 14 and 16 are machined further to provide the taper required to maintain lordosis of the spine (FIG. 15). Each of the milling steps may be performed independently using any known milling device. However, one or more of the steps may be combined into a single milling procedure using a computer controlled three dimensional milling machine. For example, radially extending wings 14 and 16 can be tapered during milling of the top and bottom surfaces of the cortical ring.

Preferably, before long bone D is cut, the bone is partially demineralized by placing the long bone in a .6NHC1 solution. By demineralizing the bone in this

1 fashion, only the walls of the intramedullary canal and the circumferential surfaces of the bone may be demineralized. The strength imparting surfaces of the radially extending wings and the radial surface of the implant will not be compromised. Moreover, the bone may be treated using a variety of bone healing enhancing  
5 technologies. For example, bone growth factors may be infused into the natural porosity of the bone and/or the bone may be infused with acid to further demineralize the bone. Both these bone treatments may be performed using the pressure flow system disclosed in U.S. Patent No. 5,846,484 which is incorporated herein by reference.

As discussed above, intervertebral implant 10 need not be formed from  
10 human cadaveric or animal bone but rather may be formed from any biocompatible material. As such, other known processes, such as molding, casting or machining techniques, may be used to manufacture the implant.

FIGS. 5-8 illustrate another embodiment of the intervertebral implant shown generally as 100. Intervertebral implant 100 is similar to intervertebral implant  
15 10 in that it includes a cylindrical body portion 112, a pair of radially extending wings 114 and 116 and a throughbore 122 having a central axis which is perpendicular to the longitudinal axis of the radially extending wings and cylindrical body portion.

However, radially extending wings 114 and 116 are tapered transversely such that wing 116 has greater height than wing 114. Implant 100 is suitable for lateral intervertebral  
20 insertion.

Intervertebral implant 100 may be manufactured using the same procedure as discussed above with respect to intervertebral implant 10 with slight variation in the milling step for forming the taper on the radially extending wings. Alternately, intervertebral implant 100 may be formed from a biocompatible material having the requisite strength requirements via any known process, i.e., molding, casting or machining.

Referring to FIGS. 16-18, intervertebral implants 10 and 100 may include retaining structure for preventing the implant from migrating from an implanted position after implantation. For example, intervertebral implant 200 (FIG. 16) includes a plurality of triangular protrusions 202 formed on the tapered surfaces of the radially extending wings. Protrusions 202 engage the adjoining vertebrae and prevent the implant from movement in relation thereto. Alternately, the protrusions may assume a variety of different configurations. For example, ridge-shaped protrusions 204 (FIG. 17) or spherically-shaped protrusions 206 (FIG. 18) may also be provided. Perforations (not shown) for receiving bone growth material may also be provided on the outer surface of the implant. It is noted that such protrusions or perforations may also be provided on the cylindrical body portion of the intervertebral implant.

FIG. 18a illustrates a variety of different protrusions which may be formed anywhere on the implant to prevent the implant from migrating from its implanted position in the intervertebral space.

FIGS. 19-22 illustrate an alternate embodiment of the presently disclosed intervertebral implant shown generally as 300. Intervertebral implant 300 includes a substantially cylindrical body portion 312 having a pair of radially extending wings 314 and 316. Radially extending wings 314 and 316 have a substantially semi-circular shape and have a height which decreases from a first end to a second end of the implant. A series of holes 320 are formed in wing 316 and a throughbore 322 extends through cylindrical body portion 312. Each of holes 320 and throughbore 322 is configured to receive bone growth material, as discussed above. Alternately, holes 320 may be formed in both radially extending wings 314 and 316.

Referring to FIGS. 23-26, the intervertebral implant, shown generally as 400, may include a substantially conical body portion 412. See also FIGS. 16-18. Conical body portion 412 decreases in height from first end 418 to second end 420 of the implant.

Referring to FIGS. 27-31, the intervertebral implant, shown generally as 500, may include only one radially extending wing 514. The other radially extending wing 516 can be either partially or completely eliminated. As illustrated in FIGS. 27-30, radially extending wing 516 has been truncated. During a surgical procedure in which two intervertebral implants are implanted between adjoining vertebrae, the side of each implant having the truncated wing (or the side from which the implant has been eliminated) is positioned adjacent to the truncated wing of the other implant. See FIG. 31.

FIG. 32 illustrates another embodiment of the intervertebral implant shown generally as 600. Intervertebral implant 600 includes a pair of cylindrical body portions 612a and 612b, a pair of radially extending wings 614 and 616, a central body portion 618 and a throughbore 622. Throughbore 622 is centrally located in implant 600 and extends through a portion of both cylindrical body portions 612a and 612b. A single implant 600 can be used in surgical procedures which typically required two intervertebral implants such as that shown in FIG. 31.

FIGS. 33-36 illustrate another embodiment of the intervertebral implant shown generally as 700. Implant 700 includes a substantially cylindrical body portion 712 having a pair of radially extending semi-circular wings 714 and a throughbore 722. The top and bottom surfaces 724 and 726 of wings 714 are convex to conform to the anatomical shape of the vertebral end plates. Alternately, the top and bottom surfaces of the wings may assume other shapes which conform to the shape of the vertebral endplates. Implant 700 further includes a slot 750 and a threaded bore 752. Threaded bore 752 extends from slot 750 into throughbore 722. Slot 750 and threaded bore 752 are configured to engage an implant insertion tool (not shown) to facilitate insertion of the implant into the intervertebral space. Although the slot and threaded bore are not shown in combination with the other implants disclosed in this application, it is contemplated that each of the implants disclosed herein may include such insertion tool engaging structure.



It will be understood that various modifications may be made to the embodiments disclosed herein. For example, radially extending wings have been described as being tapered or angled along axis both parallel and transverse to the longitudinal axis of the implant. Alternately, radially extending wings can be tapered  
5 along any axis between the parallel and transverse axis. For example, radially extending wings 814 of implant 800 are tapered along an axis which forms an angle of about 45° with respect to the longitudinal axis of the cylindrical body portion 812. See FIGS. 37 and 38. Moreover, the taper of the radially extending wings may be different than that shown but should be such as to maintain the natural alignment of the  
10 vertebrae. Alternately, radially extending wings need not be tapered. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. An intervertebral implant comprising:  
a first central body portion having a longitudinal axis; and  
at least one wing extending radially outwardly from the central body  
5 portion.
2. An intervertebral implant according to claim 1, wherein the at least  
one radially extending wing has a height which decreases along the longitudinal axis of  
the cylindrical body portion from one end of the cylindrical body portion to the other  
10 end of the cylindrical body portion.
3. An intervertebral implant according to claim 2, wherein the  
intervertebral implant includes two radially extending wings, each of the radially  
extending wings having a shape substantially the same as the other radially extending  
15 wing.
4. An intervertebral implant according to claim 1, wherein the at least  
one radially extending wing has a height which decreases in a direction perpendicular to  
the longitudinal axis of the cylindrical body portion.

20

5. An intervertebral implant according to claim 4, wherein the intervertebral implant includes a pair of radially extending wings, wherein the smallest height of one of the radially extending wings being greater than the largest height of the other of the radially extending wings.

5

6. An intervertebral implant according to claim 1, wherein the implant is manufactured from bone.

7. An intervertebral implant according to claim 6, wherein the implant  
10 is manufactured from the diaphysis or the metaphysis of a long bone.

8. An intervertebral implant according to claim 7, wherein the intramedullary canal of the long bone defines the throughbore.

9. An intervertebral implant according to claim 1, wherein the implant  
15 is manufactured from a cortical ring cut from the diaphysis or metaphysis of a long bone.

10. An intervertebral implant according to claim 1, wherein the implant  
20 is manufactured from a biocompatible material.

11. An intervertebral implant according to claim 1, further including protrusions formed on the surface of the intervertebral implant.

12. An intervertebral implant according to claim 11, wherein the protrusions are formed on the at least one radially extending wing.

13. An intervertebral implant according to claim 1, wherein the implant is formed from a bone derived composite material.

14. An intervertebral implant according to claim 1, wherein the implant is formed from a bone derived layered material.

15. An intervertebral implant according to claim 1, further including at least one opening formed in the at least one radially extending wing.

16. An intervertebral implant according to claim 1, further including at least one throughbore defined in the central body portion, the throughbore having an axis which is substantially perpendicular to the longitudinal axis of the substantially cylindrical body portion.

17. An intervertebral implant according to claim 1, further including a second central body portion having a longitudinal axis.

18. An intervertebral implant according to claim 17, wherein the first and second central body portions have parallel longitudinal axis.

19. An intervertebral implant according to claim 18, wherein the at least one radially extending wing includes two radially extending wings, one of the two radially extending wings extending outwardly from each of the first and second central body portions.

20. An intervertebral implant according to claim 1, wherein the at least one radially extending wing includes two radially extending wings.

21. An intervertebral implant according to claim 20, wherein each of the radially extending wings includes a top and a bottom surface, the top and bottom surfaces being shaped to conform to the shape of vertebral endplates.

22. An intervertebral implant according to claim 22, wherein at least one of the top and bottom surfaces of the radially extending wings is convex.

23. An intervertebral implant according to claim 1, further including engaging structure formed on the implant, the engaging structure being configured to receive an end of an implant insertion tool.

5                   24. A method for forming an intervertebral implant from the diaphysis or metaphysis of a long bone comprising the following steps:

a. making a transverse cut across a long bone to form a cortical ring;

b. milling the top surface of the cortical ring to form a first longitudinally extending crown having two upper radially extending flats; and

10                   c. milling the bottom surface of the cortical ring to form a second longitudinally extending crown having two lower radially extending flats, the upper and lower flats forming a pair of radially extending wings.

25. A method according to claim 24, wherein the first and second  
15 crowns are milled to form a substantially cylindrical body portion.

26. A method according to claim 25, wherein the first and second crowns are milled such that the intramedullary canal of the long bone extends through the substantially cylindrical body portion.

20

27. A method according to claim 26, further including the steps of:

1 milling the side surfaces of the cortical ring to form a substantially rectangular implant.

28. A method according to claim 25, further including the step of  
5 milling the upper and lower radially extending flats to vary the angle of the flats in a direction parallel to the longitudinally extending axis of the substantially cylindrical body portion.

29. A method according to claim 25, further including the step of  
10 milling the upper and lower radially extending flats to vary the angle of the flats in a direction transverse to the longitudinal axis of the cylindrical body portion.

30. A method according to claim 24, further including the following  
step:  
15 d. forming protrusions on the intervertebral implant.

31. A method according to claim 30, wherein the protrusions are formed on the radially extending wings.

32. A method according to claim 24, wherein the first and second  
20 crowns are milled to form a substantially conical body portion.

- 1                    33. A method according to claim 24, further including the step of  
forming at least one hole in at least one of the radially extending wings.
34. A method according to claim 24, wherein at least one of the upper  
5    and lower flats defining each of the radially extending wings is convex.



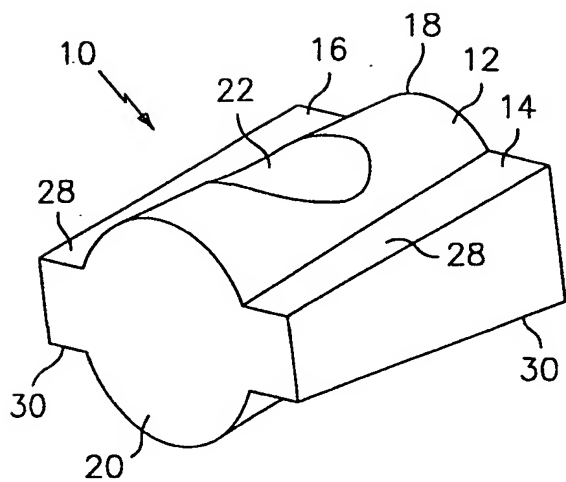


FIG. 1

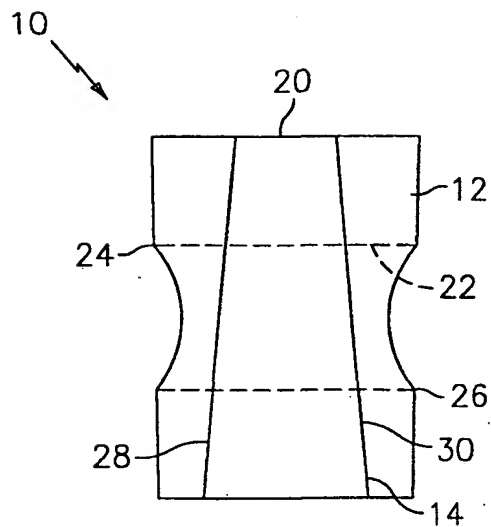


FIG. 2

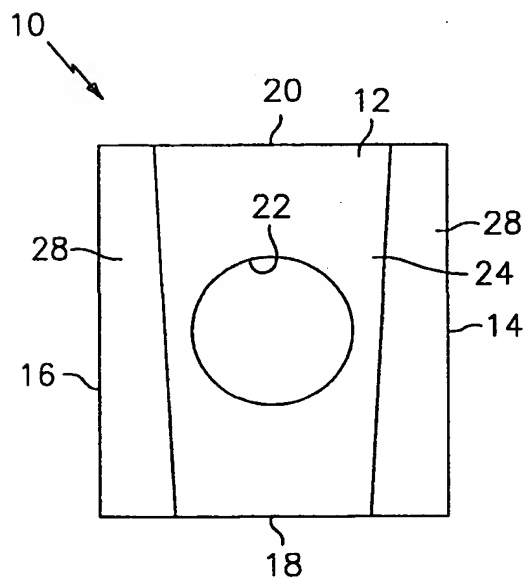


FIG. 3

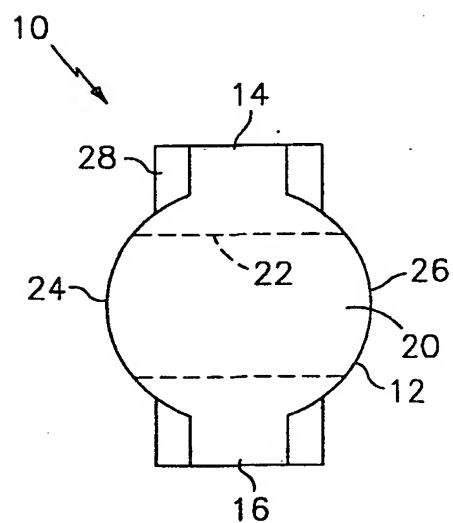
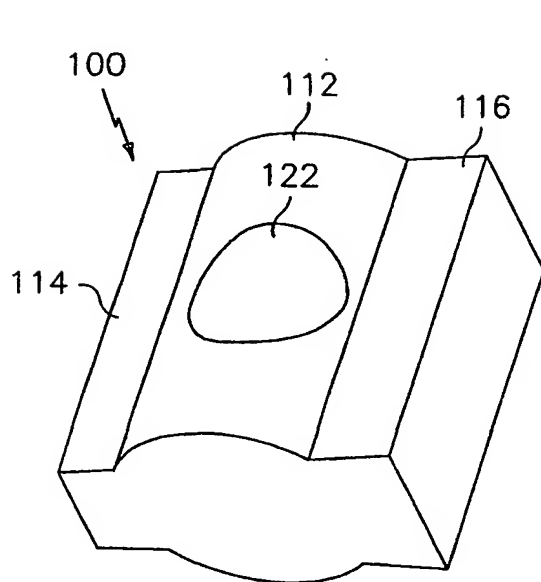
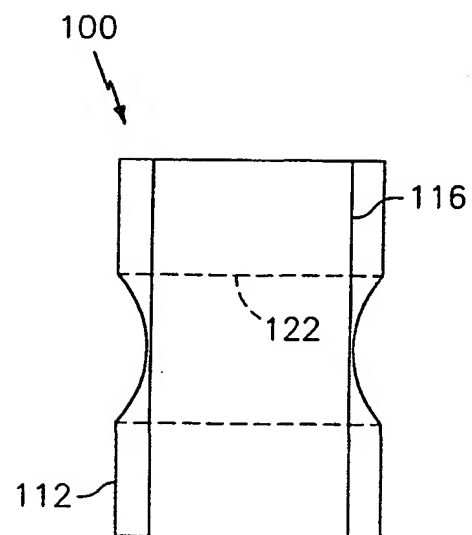
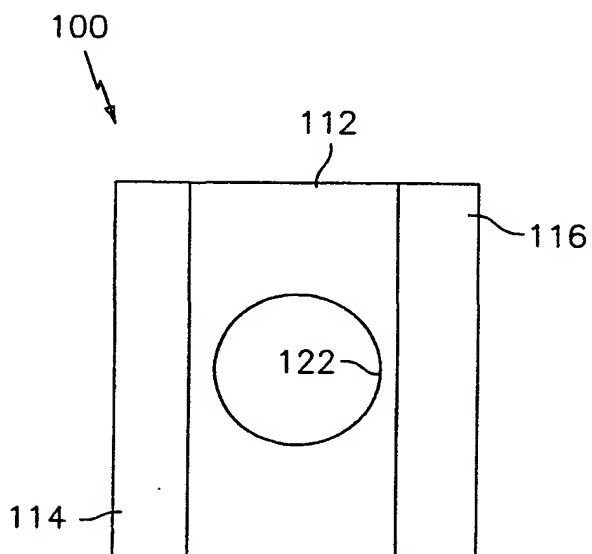
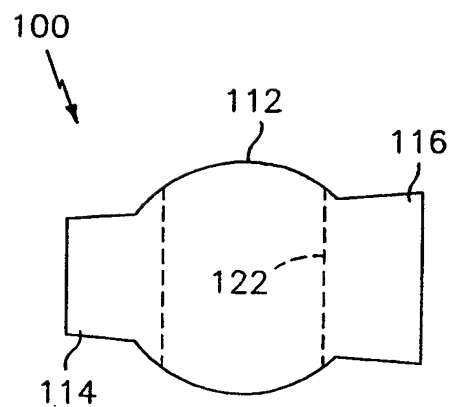


FIG. 4

**FIG. 5****FIG. 6****FIG. 7****FIG. 8**

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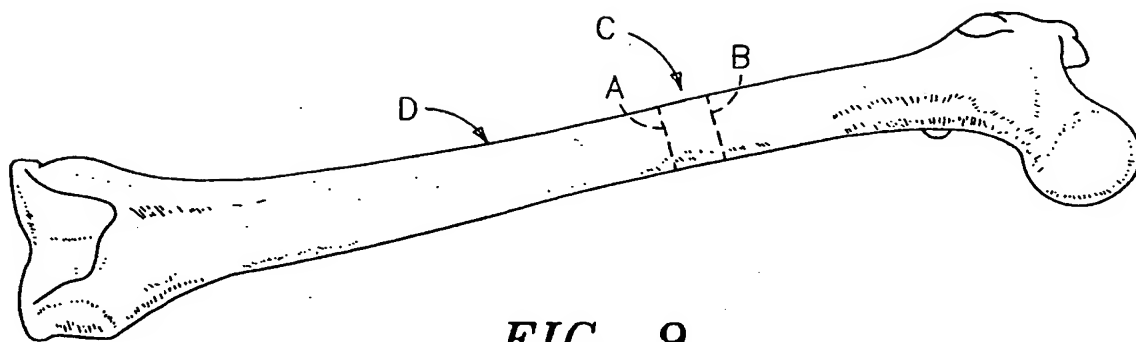


FIG. 9

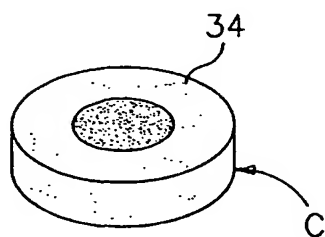


FIG. 10



FIG. 11

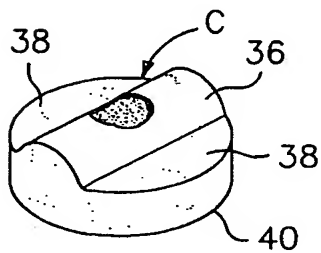


FIG. 12

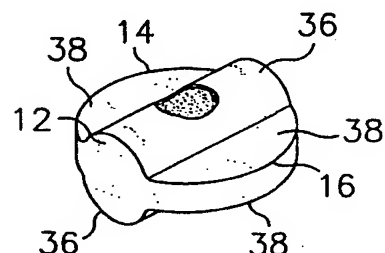


FIG. 13

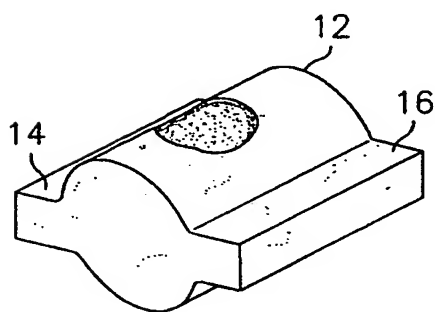


FIG. 14

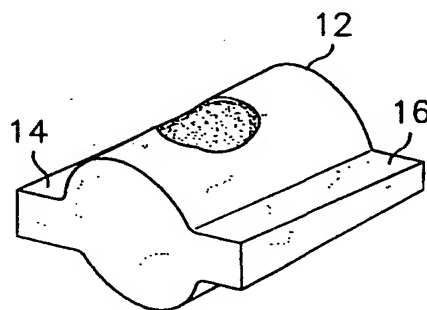
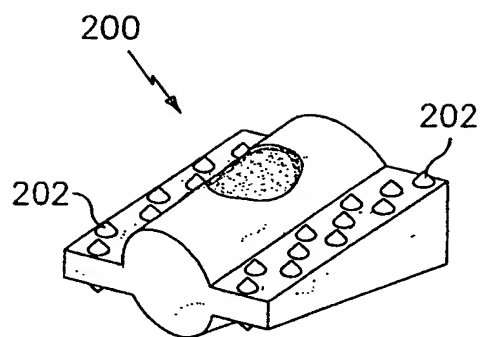
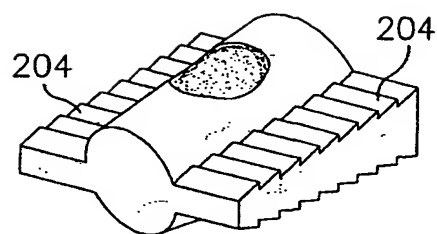


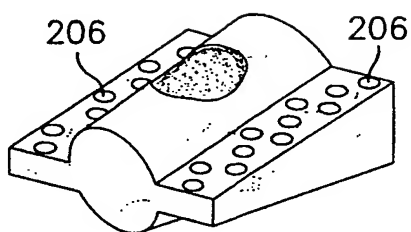
FIG. 15



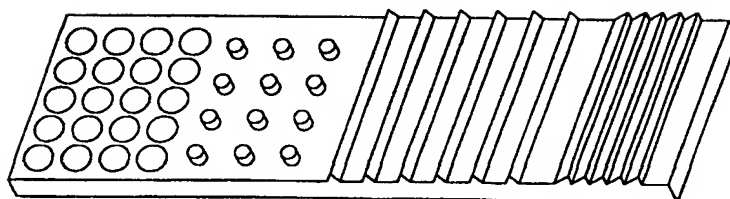
*FIG. 16*



*FIG. 17*

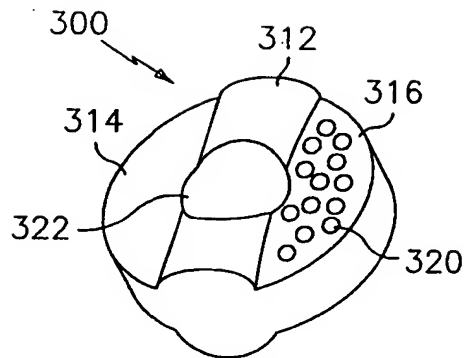
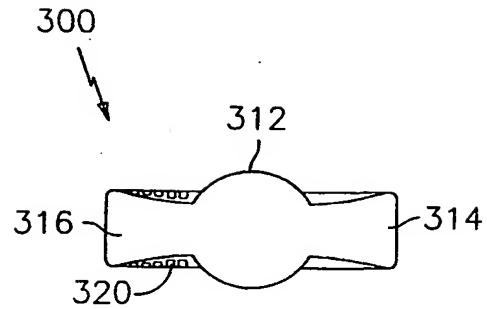
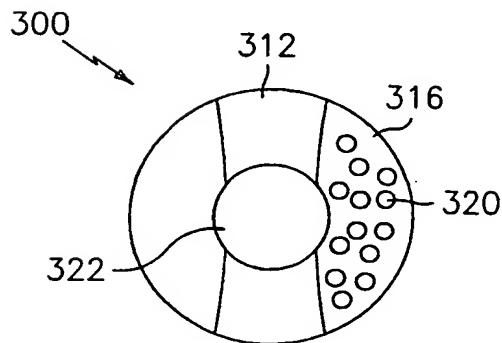
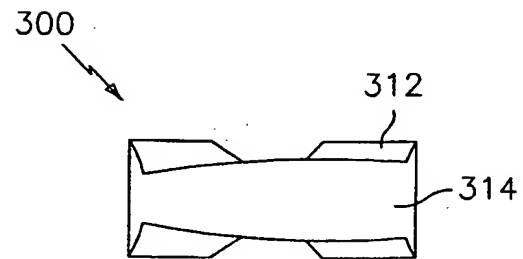
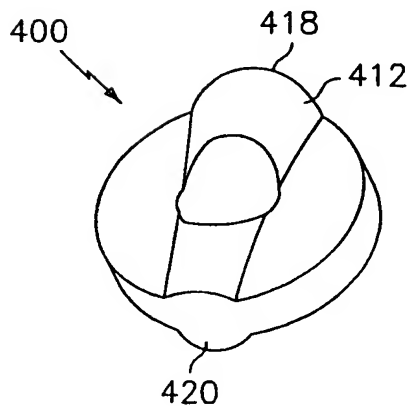
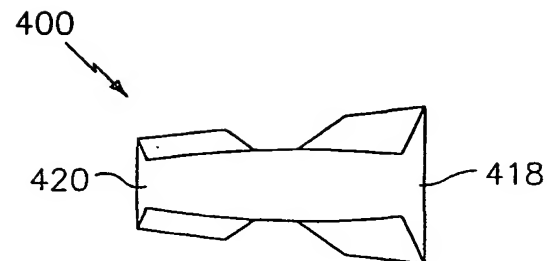


*FIG. 18*



*FIG. 18a*

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**FIG. 19****FIG. 20****FIG. 21****FIG. 22****FIG. 23****FIG. 24**

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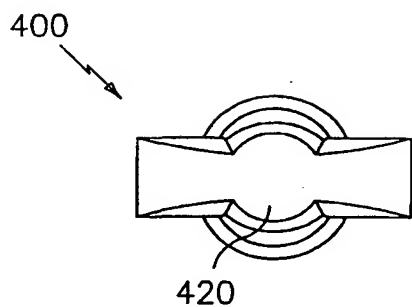


FIG. 25

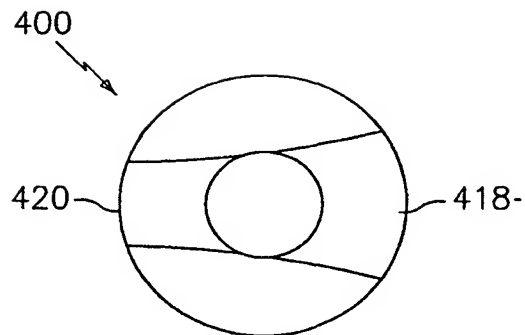


FIG. 26

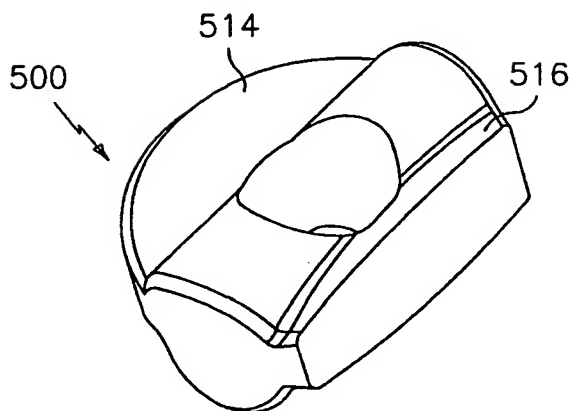


FIG. 27

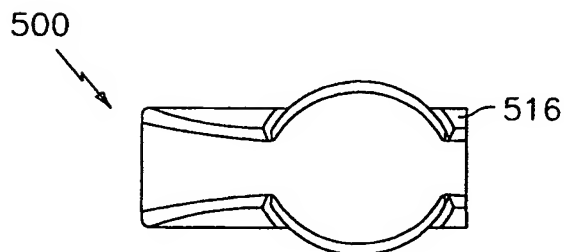


FIG. 28

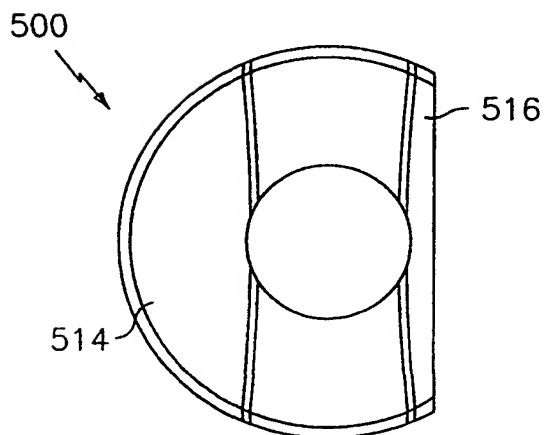


FIG. 29

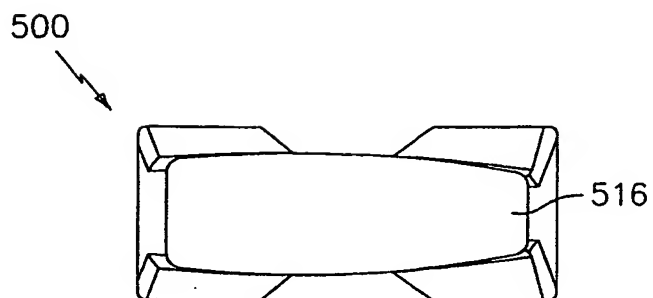


FIG. 30

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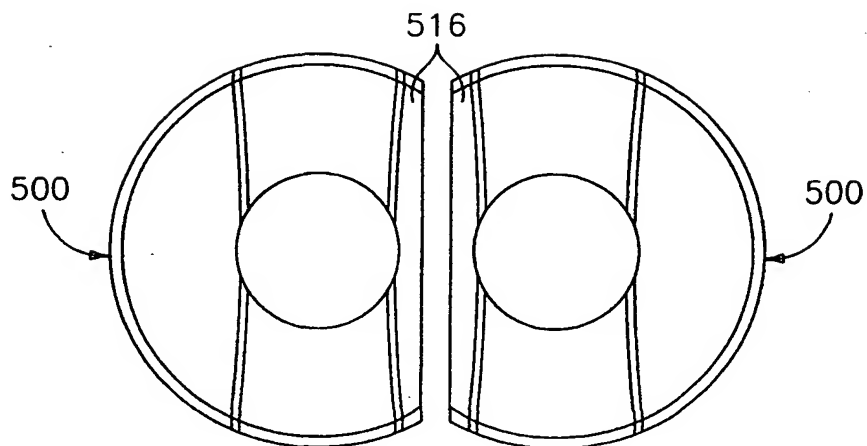


FIG. 31

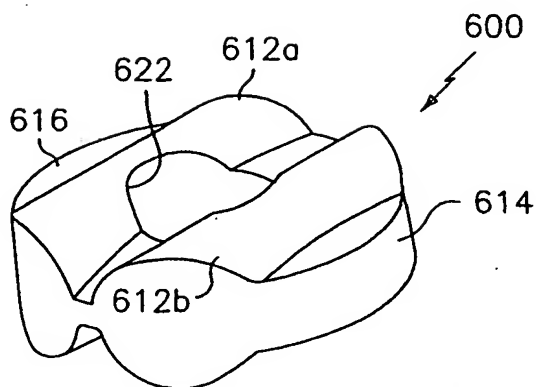


FIG. 32

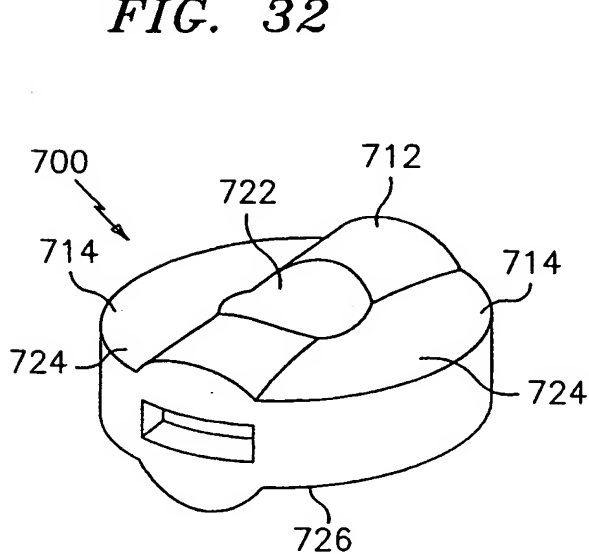


FIG. 33

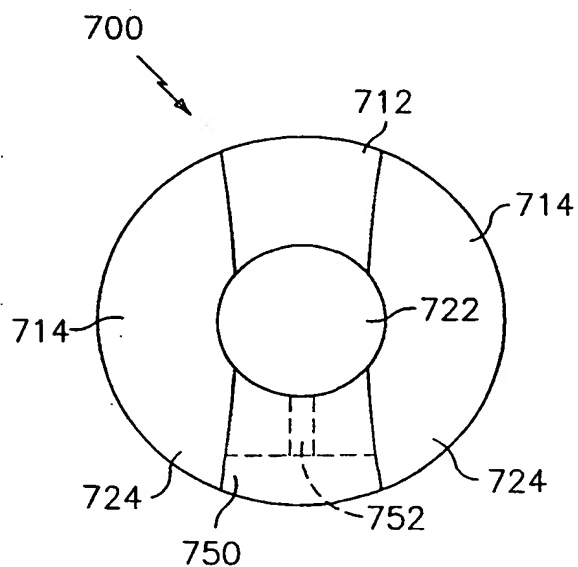


FIG. 34

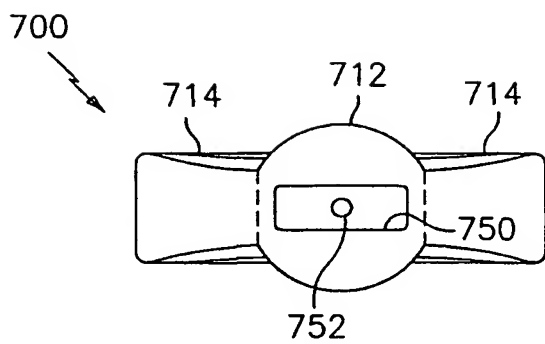


FIG. 35

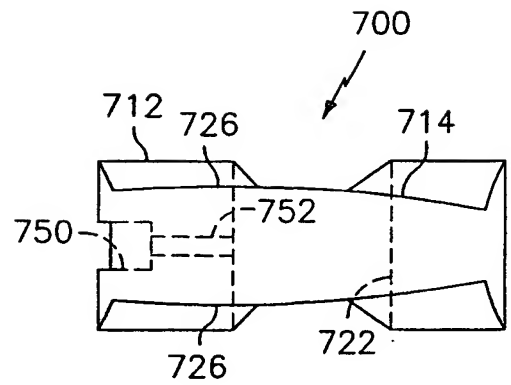


FIG. 36

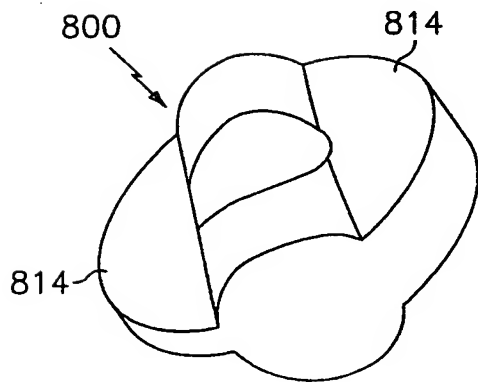


FIG. 37

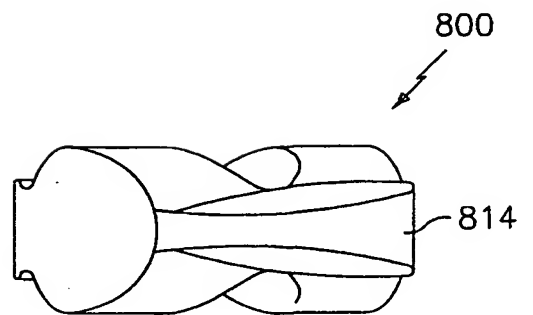


FIG. 38



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(74) Agents: DILWORTH, Peter, G. et al.; Dilworth & Barrese, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).

(81) Designated States (*national*): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

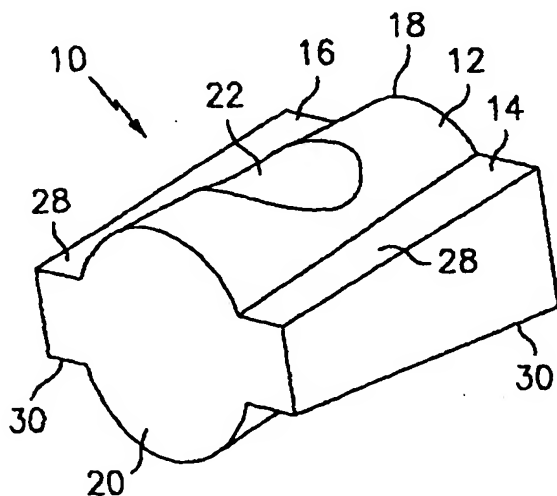
Published:

— With international search report.

(88) Date of publication of the international search report:  
30 November 2000

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INTERVERTEBRAL IMPLANT



(57) Abstract: An intervertebral implant having a composite wedge/dowel configuration is provided. The intervertebral implant includes a central body portion and a pair of radially extending wings. The radially extending wings can be tapered from a first end of the implant to the second end of the implant along an axis parallel to the longitudinal axis of the central body portion. Alternately, the radially extending wings can be tapered along an axis transverse to the longitudinal axis of the cylindrical body portion or along any other axis between parallel and transverse to the longitudinal axis. A throughbore or plurality of throughbores extend from a top surface of the implant through the implant to a bottom surface of the implant. The implant may be formed from a cortical ring cut from the diaphysis of a long bone by milling the top and bottom surfaces of the cortical ring to form the substantially central body portion and the tapered radially extending wings. The cortical ring is milled such that the intramedullary canal of the cortical ring defines a throughbore in the central body portion of the implant.

The sidewalls of the implant may be machined to form a substantially rectangular shape or the implant can be left to have a substantially circular configuration. Alternately, the implant may be formed of any biocompatible material having the requisite strength requirements via any known process, i.e., molding.

WO 00/42954 A3

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/01766

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61F2/44 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 683 394 A (RINNER JAMES A) 4 November 1997 (1997-11-04) figures 1,3,4 column 2, line 54 -column 3, line 27 column 4, line 46 - line 50	1,10, 15-18,23
A	---	19-22
X	FR 2 742 652 A (COLORADO) 27 June 1997 (1997-06-27) figures 1-3 page 7, line 15 -page 8, line 3 claims 1-11	1,2,10
Y	---	6,7
Y	US 5 814 084 A (GRIVAS NICHOLAS E ET AL) 29 September 1998 (1998-09-29) figures 1-3B claims 1,16	6,7
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

18 July 2000

Date of mailing of the international search report

26. 07 2000

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# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/01766

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	FR 2 769 827 A (SDM) 23 April 1999 (1999-04-23) figures 5-8 page 4, line 31 -page 5, line 27	1,4,5,10
E	US 6 045 580 A (MORRIS JOHN W ET AL) 4 April 2000 (2000-04-04) figures 18-30 column 4, line 37 - line 47 column 7, line 22 -column 8, line 51	1
Y		28,29,32
P,X	WO 99 38461 A (SYNTHES AG ;SYNTHES USA (US)) 5 August 1999 (1999-08-05) figures 1-6 page 2, paragraph 2 page 3, paragraph 3 page 6, paragraph 2 -page 7, paragraph 2 page 8, paragraph 1 page 9, paragraph 1 - paragraph 3 page 10, paragraph 2 - paragraph 3 claims 1,2,5,15,22-25	24,25, 30,31,34
Y		26-29,32
P,Y	WO 99 09914 A (CARTER KEVIN C ;GROOMS JAMIE M (US); SANDER TOM (US); DULEBOHN DAV) 4 March 1999 (1999-03-04) figures 1A-D,9,10A-16 page 9, line 14 -page 10, line 27 claims 1-14 claims 17-30	26,27
A	US 4 950 296 A (MCINTYRE JONATHAN L) 21 August 1990 (1990-08-21) column 2, line 21 -column 3, line 22 figures 3,4	24

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 00/01766

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-23

An intervertebral implant comprising a central body and at least one wing extending radially outwardly from the central body portion.

2. Claims: 24-34

A method for forming an intervertebral implant from the diaphysis or metaphysis of a long bone comprising a cutting and a milling step.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/01766

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5683394	A	04-11-1997	NONE	
FR 2742652	A	27-06-1997	EP 0871419 A WO 9723174 A	21-10-1998 03-07-1997
US 5814084	A	29-09-1998	AU 704228 B AU 1700597 A CA 2243152 A CZ 9802206 A EP 0876129 A HU 9902187 A JP 2000503231 T PL 328226 A WO 9725945 A	15-04-1999 11-08-1997 24-07-1997 16-06-1999 11-11-1998 29-11-1999 21-03-2000 18-01-1999 24-07-1997
FR 2769827	A	23-04-1999	WO 9920208 A	29-04-1999
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WO 9938461	A	05-08-1999	NONE	
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US 4950296	A	21-08-1990	NONE	